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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,131

09/20/2005

Karen McLachlan

2159.0640004/EKS/PAC/DLL

6721

53644

7590

10/14/2008

STERNE, KESSLER, GOLDSTEIN & FOX, P.L.L.C.
1100 NEW YORK AVE., N.W.
WASHINGTON, DC 20005

EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

10/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,131	Applicant(s) MCLACHLAN ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/05/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 7-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/12/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group III (claims 4-6, with the further election of SEQ ID NO: 21) in the reply filed on September 5, 2008 is acknowledged.

2. Claims 1-42 are pending.

Claims 1-3 and 7-42, drawn to non-elected inventions are withdrawn from examination.

Claims 4-6 are examined on the merits, to the extent the nucleic acid sequence is SEQ ID NO: 24.

Claim Objections

3. Claim 4 is objected to because of the following informality: it references non-elected sequences. Correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 4-6 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 6,623,923 (filed September 22, 1999). Applicants' claim language includes the language, "...a *nucleotide sequence* of ...SEQ ID [NO]: 24...". The claim does not require "the nucleotide sequence of SEQ ID NO: 24" or "the full length sequence of SEQ ID NO: 24", hence the following prior art reads on the claims.

The patent teaches a method of diagnosing colon cancer comprising detecting sequence 1706, which shares sequence identity with Applicants' SEQ ID NO: 24, see sequence alignment. The disclosed method comprises detecting SEQ ID NO: 24 using a nucleic acid that specifically hybridizes to a nucleotide sequence of SEQ ID NO: 24 using microarray analysis, as well as obtaining a biological sample, see the abstract; column 36, lines 29-55; and column 43, lines 28-50. "Polynucleotide primers and probes may be used to detect the level of mRNA encoding a tumor protein, which also indicative of the presence or absence of cancer.", see column 36, lines 40-43. The said primers can be used in methods of detection implementing amplification, see column 39, line 64-column 40, line 47.

RESULT 4

US-09-401-064-131/c

; Sequence 131, Application US/09401064

; Patent No. 6623923

; GENERAL INFORMATION:

; APPLICANT: Xu, Jiangchun

; APPLICANT: Lodes, Michael J.

; APPLICANT: Secrist, Heather

; APPLICANT: Benson, Darin R.

; APPLICANT: Meagher, Madeline Joy

; APPLICANT: Stolk, John A.

; APPLICANT: Wang, Tongtong

; TITLE OF INVENTION: COMPOUNDS FOR IMMUNOTHERAPY AND

; TITLE OF INVENTION: DIAGNOSIS OF COLON CANCER AND METHODS FOR THEIR USE

; FILE REFERENCE: 210121.471C2

; CURRENT APPLICATION NUMBER: US/09/401,064

; CURRENT FILING DATE: 1999-09-22

; NUMBER OF SEQ ID NOS: 371

; SOFTWARE: FastSEQ for Windows Version 3.0

; SEQ ID NO 131

; LENGTH: 554

; TYPE: DNA

; ORGANISM: Homo sapien

; FEATURE:

; NAME/KEY: misc_feature

; LOCATION: (1)...(554)

; OTHER INFORMATION: n = A,T,C or G

US-09-401-064-131

Query Match 14.6%; Score 552.2; DB 3; Length 554;

Best Local Similarity 99.5%; Pred. No. 2.4e-137;

Matches 551; Conservative 2; Mismatches 1; Indels 0; Gaps 0;

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Qy      2771 CTGCTGCCTGTGGCGTGTGTGGGCTGGATCCCTTGAAGGCTGAGTTTTTGAGGGCAGAAA 2830
          |||
Db      554 CTGCTGCCTGTGGCGTGTGTGGGCTGGATCCCTTGAAGGCTGAGTTTTTGAGGGCAGAAA 495

Qy      2831 GCTAGCTATGGGTAGCCAGGTGTTACAAAGGTGCTGCTCCTTCTCCAACCCCTACTTGGT 2890
          |||
Db      494 GCTAGCTATGGGTAGCCAGGTGTTACAAAGGTGCTGCTCCTTCTCCAACCCCTACTTGGT 435

Qy      2891 TTCCCTCACCCCAAGCCTCATGTTTCATACCAGCCAGTGGGTTTCAGCAGAACGCATGACAC 2950
          |||
Db      434 TTCCCTCACCCCAAGCCTCATGTTTCATACCANCCAGTGGGTTTCAGCAGAACGCATGACAC 375

Qy      2951 CTTATCACCTCCCTCCTTGGGTGAGCTCTGAACACCAGCTTTGGCCCCCTCCACAGTAAGG 3010
          |||
Db      374 CTTATCACCTCCCTCCTTGGGTGAGCTCTGAACACCAGCTTTGGCCCCCTCCACAGTAAGG 315

Qy      3011 CTGCTACATCAGGGGCAACCCCTGGCTCTATCATTTTCCTTTTTTGCCAAAAGGACCAGTA 3070
          |||
Db      314 CTGCTACATCAGGGGCAACCCCTGGCTCTATCATTTTCCTTTTTTGCCAAAAGGACCAGTA 255

Qy      3071 GCATAGGTGAGCCCTGAGCACTAAAAGGAGGGGTCCCTGAAGCTTTCCCACTATAGTGTG 3130
          |||
Db      254 GCATAGGTGAGCCCTGAGCACTAAAAGGAGGGGTCCCTGAAGCTTTCCCACTATAGTGTG 195

Qy      3131 GAGTTCTGTCCCTGAGGTGGGTACAGCAGCCTTGGTTTCCTCTGGGGGTTGAGAATAAGAA 3190
          |||
Db      194 GAGTTCTGTCCCTGAGGTGGGTACAGCAGCCTTGGTTTCCTCTGGGGGTTGAGAATAAGAA 135
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Art Unit: 1643

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Qy      3191 TAGTGGGGAGGGAAAACTCCTCCTTGAAGATTTCTGTCTCAGAGTCCCAGAGAGGTAG 3250
          |||||||||||||||||||:|||||||||||||||||
Db      134 TAGTGGGGAGGGAAAACTCCTCCTTGAAGATTTCTGTCTCAGAGTCCCAGAGAGGTAG 75

Qy      3251 AAAGGAGGAATTTCTGCTGGACTTTATCTGGGCAGAGGAAGGATGGAATGAAGGTAGAAA 3310
          |||||||||||||||||||:|||||||||||||||||
Db      74 AAAGGAGGAATTTCTGCTGGMCTTTATCTGGGCAGAGGAAGGATGGAATGAAGGTAGAAA 15

Qy      3311 AGGCAGAATTACAG 3324
          |||||||||||||||
Db      14 AGGCAGAATTACAG 1

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6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/509,131
Art Unit: 1643

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Alana M. Harris, Ph.D.
October 1, 2008
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643